

#### REMARKS

Claims 1-15 were pending. Claims 1-15 have been canceled and claims 16-41 have been added to more accurately point out what Applicants regard as their invention and to place the claims in conformity with U.S. patent practice.

# Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 15, under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use this invention. Specifically, the Examiner deemed that claim 15 was directed to formulation for use in therapy of any illness, any cardiovascular disorder or cerebrovascular disorder, any form of diabetes or pre-diabetes, any form of psychiatric disorder, any form of neurological or neurodegenerative disorder, any form of kidney disorder, any form of obesity and any form of cancer.

Additionally, claims 1-15 were rejected under 35 U.S.C.

112, first paragraph, because the specification, while being enabling for methyltetrahydrofolate, does not reasonably provide

enablement for a compound related to folic acid with similar biological activity.

With regard to the method of treatment claims, claims 40 and 41, Applicants respectfully submit that most of the diseases and disorders as recited show some response to EFA treatment.

The present invention improves the EFA treatment response of these diseases.

Applicants respectfully submit that compounds related to folic acid having similar biological activity are fully enabled. Specifically, any nutritional textbook describes the variety of compounds that are considered to be related to folic acid which have similar biological activity. Thus, one of ordinary skill in the art need only select one of these compounds found in a nutritional textbook to practice the present invention as claimed. No undue experimentation is required.

Therefore, Applicants respectfully submit that the rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

## Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-15 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The Examiner deemed that:

- a) Claims 1 and 5 are substantial duplicates.
- b) Claims 1-3 are indefinite in that the same improperly depend from FIG 1.
- c) Claims 10-11, the phrase "preferably" render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.
- d) Claim 15, the phrase "including" render the claim indefinite because it is unclear whether the limitation following the phrase are part of the claimed invention.

Applicants respectfully submit that the claims as amended obviate this rejection. Thus, Applicants respectfully submit that the claims as amended are clear and definite and that the rejection under 35 U.S.C. 112, second paragraph, may properly be withdrawn.

## Rejections Under 35 U.S.C. §§ 102 and 103

The Examiner rejected claims 1-15 under 35 U.S.C. §102(a) as the Examiner deemed that claims are anticipated. The

Examiner also rejected claims 1-15 under 35 U.S.C. §103(a) as being obvious over EP 0,305,097, EP 0,198,804, or WO 99/03482.

Applicants respectfully submit that none of the prior art, alone or in combination, teach or suggest the present invention as claimed. Specifically, the prior art discloses formulations wherein essential micronutrients other than EFAs and homocysteine lowering agents are present. The present invention as claimed makes clear that the formulation does not include significant amounts of other micronutrients.

As none of the prior art cited by the Examiner, alone or in combination, teach or suggest each and every element of the present invention as claimed, the rejection under 35 U.S.C. 103 may be properly withdrawn.

## CONCLUSION

Accordingly, in view of the foregoing amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims to allow these claims and to find this application to be in allowable condition.

. If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is invited to telephone the undersigned to arrange for such a conference.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Bv

John d. Holman

Reg. No. 22,769

400 Seventh Street, N.W. Washington, D.C. 20004-2201

(202) 638-6666

Date: November 9, 2001

Atty. Docket: 1398/P65773US0

JCH/SKS/lb